Claim 39, and claims 40-42, 45, 46, 87, 89, and 90 dependent thereon, recite a device for determining a position and a change in the position of an anatomical structure for use with a surgical navigation system. The device comprises a substrate including means for removably attaching the substrate to an outer surface of a body, wherein the body includes an anatomical structure, a sensor attached to the substrate that can be tracked by the surgical navigation system, a magnetic transmitter attached to the substrate, and a magnetic sensor comprising means for attachment to the anatomical structure. The magnetic transmitter and the magnetic sensor are utilized to determine a position of the anatomical structure. The device further includes a first circuit for calculating a global position of the anatomical structure by correlating a position of the sensor and the position of the anatomical structure and a second circuit for displaying the global position of the anatomical structure on a display unit.

Claim 56, and claims 57-60, 63, 76-79, 84, and 91-95 dependent thereon, recite a method for determining a position and a change in the position of an anatomical structure using a surgical navigation system that includes the step of attaching a substrate in a removable manner to an outer surface of a body, the substrate having an associated sensor and having a positional device on the substrate for determining a position of the anatomical structure relative to the sensor, wherein the body includes an anatomical structure spaced interiorly from the outer surface and the sensor is tracked by the surgical navigation system. The method further includes the steps of determining the position of the anatomical structure and tracking the position of the anatomical structure with the surgical navigation system.

In contrast, Bova discloses a system 10 including a 3D ultrasound probe 22 that is placed in contact against the body of a patient to provide 3D imaging data of the patient to a processor 20. The system 10 further includes probe position markers 26 on the ultrasound probe 22 and patient position markers 16, 116 that are secured directly to the patient (see, e.g., FIG. 1) or secured to a body frame 134 that immobilizes the patient (see, e.g., FIG. 2). A camera system 28 tracks the probe position markers 26 and the patient position markers 16, 116 and the processor 20 converts the 3D imaging data into data relative to the fixed frame of reference of the patient position markers 16 to provide real time 3D imaging data for use in performing medical procedures.

Acker discloses a frame structure 30 that supports pairs of coils 34, 36, and 38. Each pair of coils 34, 36, 38 is disposed coaxially along respective orthogonal XYZ axes, wherein the XYZ axes establish a frame of reference of the frame structure 30. The coils 34, 36, 38 are driven to generate a specific arrangement of magnetic fields including uniform and gradient magnetic fields oriented parallel to and perpendicular with each of the XYZ axes. See, e.g., Acker column 12, line 5 – column 13, line 27. Acker further discloses a probe 50 that includes a sensor 60 mounted on an end thereof. The sensor 60 generates voltage signals when placed in the magnetic fields generated by the coils 34, 36, 38 and a computer 46 interprets such voltage signals to determine a position and orientation of the sensor 60 within the frame of reference of the frame structure 30. In use, a patient is positioned within the frame structure 30 and the probe 50 is inserted into the body of the patient. The magnetic fields described above are generated and the position and orientation of the sensor 60 is determined to track the position and orientation of the tip of the probe 50.

Mangiardi discloses a marker that includes a marking pin 3 and a wire 4 that extends from the marking pin 3. The marking pin 3 is secured to a bone of a patient with the wire 4 extending out of the patient's skin to mark a position and angle for use in a surgical procedure.

Regarding the rejection of claims 56-60 and 79, the examiner states that Bova teaches "a substrate capable of being removably mounted to an outer surface of a body." Office action page 3. However, claims 56-60 and 79 actually recite the step of attaching a substrate in a removable manner to an outer surface of a body. As discussed in detail in the previous Amendment B, Bova only discloses an ultrasound device 22 that is merely placed in contact against the body of a patient. Bova does not disclose or suggest any structure for attaching the ultrasound device to an outer surface of a body, much less actually attaching the ultrasound device to the outer surface of the body. Therefore, the rejection of claims 56-60 and 79 as anticipated by Bova should be withdrawn.

Further, the applicants traverse the assertion in the Office action that "Bova et al. teaches the limitations as discussed above" to form the basis of the obviousness rejections of claims 39-42, 45, 46, 63, 76-78, 84, 87, and 89-95 because Bova does not disclose or suggest a substrate including means for removably attaching the substrate to an outer surface of a body or a step of attaching a substrate in a removable manner to an outer surface of a body, as discussed above. Therefore, the

obviousness rejection of claims 39-42, 45, 46, 63, 76-78, 84, 87, and 89-95, should be withdrawn.

In addition to the deficiencies of Bova discussed above, there is no motivation or suggestion to modify Bova with Acker, as suggested in the Office action, because to do so would render Bova unsatisfactory for its intended purpose. MPEP §2143.01(V); *see also In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984). More specifically, an intended purpose of Bova "is to provide 3D imaging data," which is accomplished though use of a 3D ultrasound probe. Bova column 3, lines 34-35; *see also* column 2, lines 42-50; and column 6, lines 25-27. However, the magnetic sensor of Acker is only able to provide positional information, which does not disclose or suggest 3D imaging data. Therefore, it would not have been obvious to replace the ultrasound transducer of Bova with the magnetic sensor of Acker because to do so would render Bova unsatisfactory for its intended purpose of providing 3D imaging data. MPEP §2143.01(V).

Applicants further traverse the assertion in the Office action that Acker teaches "a magnetic sensor with means for attachment to the anatomical structure (claim 41 for example)." Office action page 4. Claim 41 refers to the sensor 60 mounted to an end of the probe 50, wherein the probe 50 is adapted for insertion into a patient. However, the probe 50 is not an anatomical structure. Therefore, the examiner has not identified any disclosure or suggestion in Acker of a magnetic sensor that includes means for attachment to an anatomical structure, as recited by claims 39-42, 45, 46, 87, 89, and 90, and for this additional reason, the rejection of such claims should be withdrawn.

Still further, the examiner states in the Office action that it would have been obvious "to modify Bova et al. to instead use the magnetic sensor in place of Bova et al.'s ultrasound transducer along with the magnetic sensor in order to provide global positioning of the anatomical structure relative to the room's fix [sic] frame of reference." Office action page 4. However, the claims at issue actually recite a magnetic transmitter, not a magnetic sensor, attached to a substrate including means for removably attaching the substrate to an outer surface of a body and a magnetic sensor comprising means for attachment to an anatomical structure. Therefore, the Office action has not identified any disclosure or suggestion in the applied references to teach the actual limitations recited by the claims at issue. For this additional reason, the applicants respectfully request withdrawal of the pending rejections.

Consideration and allowance of the claims at issue are respectfully requested. If there are any issues that can be resolved by telephone, the examiner is invited to call the undersigned.

Deposit Account Authorization

The Commissioner is hereby authorized to charge any deficiency in any amount enclosed or any additional fees, which may be required during the pendency of this application under 37 C.F.R. §§ 1.16 or 1.17, except issue fees, to Deposit Account No. 50-1903.

Respectfully submitted,

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